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10/540,516

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,516	<b>Applicant(s)</b> SOUSSALINE ET AL.	
	<b>Examiner</b> P. Kathryn Wright	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) 2-11, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12-14 and 20-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/13/2005;06/23/2005</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of species A (V) and species B (ii) in the reply filed on April 24, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "means for determining" in claim 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 14120 in Fig. 1, see page 23, last paragraph.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

6. The disclosure is objected to because of the following informalities: it is missing a Brief Description of the Several Views of the Drawing(s) designation: See MPEP § 608.01(f) and 37 CFR 1.74.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 recites "means for determining". The Examiner has interpreted this limitation as a means-plus-function limitation covered by 35 USC 112, sixth paragraph. This interpretation is proper since the claim limitation recites "means for" language, and

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the “means for” is not modified by sufficient structure for achieving the specified function. A means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function. For claims falling under 35 USC 112, sixth paragraph, Examiners are required to construe claims as covering the corresponding structure, material, or acts described in the specification and equivalents thereof, see *In re Donaldson Co.*, 29 USPQ2d 1845 (Fed. Cir. 1994). However, the written description fails to link or associate a particular structure, material, or acts to the function recited in the means plus function claim limitation. Nor would one skilled in the art would have known what structure, material, or acts perform the function recited in the “means for determining”.

Applicant fails to set forth an adequate written description as required by the first paragraph of section 112.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 12-14, and 20-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a plurality of “Peltier-type” heating and cooling elements. It is not clear what Applicant means by a “Peltier-type” element. Clarification is required.

Claim 12 recites, in part, wherein the excitation means comprises a lamp and a laser whose radiations follow the same optical path due to a swinging mirror that can pivot around an axis between two positions so as to direct one of these two radiations

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toward the chip. This configuration is shown in Fig. 3D (see also page 22, line 38-page 23, line15.) Claims 13 and 14, depend directly and indirectly from claim 12. Claim 13 recites, in part, wherein the laser excitation takes place by direct illumination of the molecules, that is, no element being interposed between the laser and the chip, as shown in Fig. 3A and defined in the specification at page 21, lines 1-8. It is not clear how the optical path of the laser can be directed by a swinging mirror (i.e., element interposed between the laser and the chip) and provide direct illumination of molecules on the chip. These two claimed configurations appear to be contradictory.

Claim 20 recites the reading means also comprises a processing mean. Claim 25 indirectly depends from claim 20 and also recites the reading means comprising processing means. It is not clear whether the processing means in claim 25 is the same as or different than the processing means previously recited in claim 20.

As discussed above, claim 22 recites “means for determining”. The Examiner has interpreted this limitation as a means-plus-function limitation covered by 35 USC 112, sixth paragraph. However, the specification does not set forth the corresponding structure. Thus, it is unclear and indefinite what structure Applicant is intending to encompass with the “means for determining” limitation.

Since Applicant fails to set forth an adequate disclosure, applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

13. Claims 1 and 20-22, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Khomyakova et al., (“Innovative Instrumentation for Microarray Scanning and Analysis: Application for Characterization of Oligonucleotide Duplexes Behavior”), *Cellular and Molecular Biology*, Vol. 50, No. 3, pages 217-224, published May 2004, hereinafter “Khomyakova”.

Khomyakova teaches a device for reading and analyzing chips, comprising:

- (a) a table for receiving a chip intended to characterize at least one sample;
- (b) means of exciting (i.e., mercury lamp and laser; see Fig. 1) the molecules or the cells of the chip, after reaction with other molecules;
- (c) means of reading and analyzing (CCD camera) the molecules subjected to excitation;

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(d) a unit for controlling the temperature of the table, the control unit being connected to a module consisting of a plurality of Peltier-type heating/cooling elements (i.e., thermotable) arranged opposite various spots on the surface of the table (see page 219, left column); and

(e) it is expected that the temperature control system includes at least one table temperature sensor also connected to the control unit (see page 219, left column).

As to claim 20, Khomyakova teaches the reader also comprises processing means comprising a microprocessor (i.e., inside computer) and connected to the temperature control unit and also to the reading means (see Fig. 1).

Regarding claim 21, the Khomyakova reader is connected to the computer which comprises means of storing (i.e., memory) reference curves of the response of the matches and mismatches of the molecules to the excitation means as a function of the temperature (see page 221, left column).

With respect to claim 22, as best understood, the storage means of Khomyakova is connected to means for determining (computer) a melting temperature for the matches and mismatches of the molecules, from said reference curves (see also page 223, left side column).

14. Claims 1 and 20, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao et al., (US Patent Pub. No. 2002/0022226), hereinafter "Nakao".

Nakao teaches a device for reading and analyzing chips, comprising:



- (a) a table 20 for receiving a chip 10 intended to characterize at least one sample;
- (b) means of exciting 50 the molecules or the cells of the chip, after reaction with other molecules;
- (c) means of reading and analyzing 55 the molecules subjected to excitation;
- (d) a unit 40 for controlling the temperature of the table, the control unit being connected to a module consisting of a plurality of Peltier-type heating/cooling elements 31, 32 arranged opposite various spots on the surface of the table; and
- (e) at least one table temperature sensor 33 also connected to the control unit.

As to claim 20, Nakao teaches the reader also comprises processing means comprising a microprocessor (within the computer 40), the microcomputer is connected to the temperature control unit and also to the reading means (see Fig. 2).

15. Claims 1 and 20-26, as best understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Sundberg et al., (US Patent Pub. No. 2005/020470), hereinafter "Sundberg".

Sundberg teaches a device for reading and analyzing chips, comprising:

- (a) a table (stage) for receiving a chip 400 intended to characterize at least one sample (see entire document, in particular paragraph [0130]);
- (b) means of exciting the molecules or the cells of the chip, after reaction with other molecules (see entire document, in particular paragraphs [0029] and [0143]);

(c) means of reading and analyzing 206 the molecules subjected to excitation (see entire document, in particular paragraphs [0135]-[0142];

(d) a unit for controlling the temperature of the table 210; the control unit being connected to a module consisting of a plurality of Peltier-type heating/cooling elements arranged opposite various spots on the surface of the table (see entire document, in particular [0103]-[0104], [0111], and [0161]; and

(e) at least one table temperature sensor 33 also connected to the control unit (see entire document, in particular paragraph [0132] and [0151]).

As to claim 20, Sundberg teaches the reader also comprises processing means comprising a microprocessor 204 and connected to the temperature control unit 210 and also to the reading means 206 (see entire document, especially paragraphs [0148]-[0155] and [0159] and Fig. 2).

Regarding claim 21, Sundberg teaches the reader comprises means of storing reference (memory) curves of the response of the matches and mismatches of the molecules to the excitation means as a function of the temperature (see entire document in particular paragraphs [0096] and [0155]).

With respect to claim 22, Sundberg teaches that the storage means are connected to means for determining (i.e., computer/monitor 210/216) a melting temperature for the matches and mismatches of the molecules, from the reference curves (see entire document in particular paragraphs [0096] and [0155]).

As to claim 23, note that it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability

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to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Nevertheless, Sundberg teaches the temperature control unit for controlling the functioning of the reader according to a "static" mode in which pre-established reference curves of the response of the matches and mismatches of the molecules as a function of the temperature are used to establish a set temperature that can be transmitted, by the temperature control unit, so as to control the temperature of said table (see entire document, in particular paragraphs [0041]-[0088]).

Regarding claim 24, again note it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. Nevertheless, Sundberg teaches that the temperature control unit for controlling the functioning of the reader according to a "dynamic" mode in which the temperature control unit controls a given change in temperature on the table, and, during this change in temperature: the reading means collect, in real time, the response of the molecules associated with the various spots on the chip to the excitation by the excitation means, and transmit said response to processing means, storage means store, for each spot on the chip, the change in response of the molecule as a function of the temperature. (see entire document, in particular paragraphs [0041]-[0088]).

As to claim 25, as discussed above, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. Nevertheless, Sundberg teaches the reader comprises a

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processing means (computer 204) for establishing, for each molecule, at the end of the storage of the change in response, a diagnosis of state of the molecule.

Regarding claim 26, diagnosis of state is a match/mismatch diagnosis (see for example paragraphs [0062]-[0066]).

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 12-14, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Khomyakova or Sundberg in view of Osgood et al., (US Patent No. 6,355,934), hereinafter "Osgood".

Khomyakova teaches the excitation means comprises a lamp and a mercury laser (see Fig. 1). Similarly, Sundberg teaches the excitation means comprise one or more of mercury lamps and/or lasers, see paragraph [0029]. However, neither Khomyakova or Sundberg explicitly teaches a lamp and a laser whose radiations follow the same optical path due to a swinging mirror that can pivot around an axis between two positions so as to direct one of these two radiations toward the chip. However, the use of rotating mirrors to direct the radiation toward a biochip is considered conventional in optical scanning systems, see for example Osgood.

Osgood teaches the excitation means 60 includes a plurality of radiation sources 100 (e.g., lasers) whose radiations follow the same optical path due to a swinging mirror 70 that can pivot around an axis 93 between two positions so as to direct the radiation toward the chip 30, see for example Fig. 3. As to claim 14, Osgood teaches the optical system comprises narrow bandwidth excitation light filters, narrow bandwidth emission light filters 83, and a beam separator (beamsplitter), see for example col. 5, line 44-col. 6, line 24. Osgood also teaches that when properly aligned, mirror 70 will completely capture the specular reflection of the excitation beam and redirect the specular

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component of the radiant energy away from the detector and, preferably to the radiation sources, thus enhancing the system signal-to-noise ratio.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the optical system of Khomyakova or Sundberg, the pivotal mirror of Osgood, since this allows for the mirror to be aligned so it will completely capture the specular reflection of the excitation beam and redirect the specular component of the radiant energy away from the detector and, preferably to the radiation sources, thus enhancing the system signal-to-noise ratio (see summary of invention section).

As to claim 13, as best understood, Khomyakova teaches an optical system is interposed between the lamp and the molecules to be excited, whereas the laser excitation takes place by direct illumination of the molecules, see Fig. 1.

### ***Conclusion***

20. No claims are allowed.

21. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure as general background information related to Applicant's field of endeavor.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/  
Examiner, Art Unit 1797